मिसिलस.- 8(106)/2022/डी.पी/एनपीपीए-डीवी-II F. No. 8(106)/2022/DP/NPPA-Div. II

कार्यवाहीस. : 238/106/2022/F Proceeding No: 238/106/2022/F

Minutes of the 238th (overall) and 106th meeting of the Authority under DPCO, 2013 held on 30.12.2022 at 11:00AM

The 238th meeting of the Authority (overall), which is the 105th meeting under the DPCO, 2013, was held on 15th December at 03:30 PM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri G. Venkatesh, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure was present and joined through video-conferencing
- (iii) Shri Saikat Sarkar, Economic Adviser, Department of Economic Affairs

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare also was present.

- 1.1 The following officers of NPPA attended the meeting and assisted the Authority in its deliberations:
 - (i) Shri Manmohan Sachdeva, Advisor (Cost-I)
 - (ii) Ms. Rashmi Tahiliani, Join Director (Pricing)
 - (iii) Shri Jegan, Joint Director (Medical Devices)
 - (iv) Shri Mahaveer Saini, Deputy Director (Pricing)
 - (v) Shri Rajesh, DD (Medical Devices)
 - (vi) Ms. Yuvika Panwar, Assistant Director (Overcharging/Pricing)

II. Agenda items

- 1. Agenda item no. 1 Confirmation of Minutes of the 105th Meeting held on 15.12.2022
- 1.1 The Authority confirmed the minutes without any change.
- 2. Agenda item no. 2 (a) Action Taken Report (ATR) on decisions taken by NPPA in its 105th Meeting held on 15.12.2022
- 2.1 Noted.
- 3. Agenda item no. 3 Status of New Drug applications
- 3.1 Noted.
- 4. Agenda item no. 4 New Drug applications for Price fixation under Para 5 and Para 15 of DPCO, 2013



4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (x)(total 36 Form I applications containing retail price fixation of 36 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 36(Thirty Six) new drugs under Para 5 and 15 of the DPCO 2013, as detailed in **Table 1**:

Table No. 1: Retail price fixation of new drugs

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)	
(1)	(2)	(3)	(4)	(5)	(6)	
4 (i) a	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	sphate eq. to 1 Tablet		12.45	
4 (i) b	Sitagliptin Phosphate and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Natco Pharma Ltd.	13.25	
4 (ii) a	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s USV Pvt. Ltd.	26.78	
4 (ii) b	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s USV Pvt. Ltd.	28.57	
4 (ii) c	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	22.90	
4 (ii) d	Dapagliflozin, Sitagliptin and Metformin	Each film coated bilayered tablet contains: Dapagliflozin Propanediol	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure	24.10	



Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)	
(1)	(2)	(3)	(4)	(5)	(6)	
	Hydrochloride (as Extended Release) Tablets	Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)		Pharmaceuticals Limited		
4 (ii) e	e Dapagliflozin, Sitagliptin and Metformin Dapagliflozin Propanediol		M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	30.11		
4 (ii) f	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Release) Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	28.72	
4 (ii) g	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Alembic Pharmaceuticals Limited	17.85	
4 (ii) h	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	gliflozin, Each film coated bilayered tablet contains: Pharmaceuticals / Pharmaceuticals Limited see) Sitagliptin Phosphate 1 Tablet		18.75		
4 (ii) i	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release)	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate	1 Tablet	M/s Exemed Pharmaceuticals / M/s Glenmark Pharmaceuticals Limited	30.11	



Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablets	Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)			
4 (ii) j	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Glenmark Pharmaceuticals Limited	28.72
4 (ii) k	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	21.00
4 (ii) l	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	19.00
4 (ii) m	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	27.67
4 (ii) n	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Life Sciences Limited	25.89



Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)	
(1)	(2)	(3)	(4)	(5)	(6)	
		500mg (as Extended Release)				
4 (ii) o	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayeredtablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s ExemedPharmaceutic als / M/s Cipla Ltd.	28.72	
4 (ii) p	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	30.11	
4 (ii) q	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Micro Labs Limited	24.10	
4 (ii) r	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Micro Labs Limited	25.89	
4 (ii) s	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Torrent Pharmaceuticals Limited	29.26	



Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)	
(1)	(2)	(3)	(4)	(5)	(6)	
	Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)		Pharmaceuticals / M/s Torrent Pharmaceuticals Limited	(6)	
4 (ii) u	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Abbott Healthcare Pvt. Ltd.	20.53	
4 (ii) v	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Abbott Healthcare Pvt. Ltd.	19.64	
4 (ii) w	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Lupin Limited	20.53	
4 (ii) x	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Lupin Limited	22.32	
4 (ii) y	Dapagliflozin, Sitagliptin and Metformin Hydrochloride	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cadila Pharmaceuticals Ltd.	27.73	



Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)	
(1)	(2)	(3)	(4)	(5)	(6)	
	(as Extended Release) Tablets	Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)				
4 (ii) z	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cadila Pharmaceuticals Ltd.	29.26	
4(iii)	Metronidazole, Furazolidone & Dicyclomine Hydrochloride tablets	Each uncoated tablet contains: Metronidazole IP 200mg Furazolidone IP 100mg Dicyclomine Hydrochloride IP 10mg	1 Tablet	M/s Dallas Drugs Pvt. Ltd. / M/s Micro Labs Pvt. Ltd.	1.08	
4(iv)	Atorvastatin &Bempedoic Acid Tablet	Each film coated table contains: Atorvastatin Calcium IP eq. to Atorvastatin 80mg Bempedoic Acid 180mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Torrent Pharmaceuticals Limited	48.00	
4(v)	Telmisartan and Bisoprolol Tablets	Each film coated table contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Micro labs Ltd.	10.92	
4(vi)	Lidocaine Patch 5%	Each Adhesive Patch Contains: Lidocaine 700mg in an aqueous base (50mg per gm adhesive)	1 Patch	M/s Hetero Healthcare Ltd.	44.64	
4(vii)	Levetiracetam Infusion	Each 100ml contains: Levetiracetam IP 500mg Sodium Chloride IP 820mg Water for Injections IP q. s.	1 ml	M/s Akums Drugs & Pharmaceuticals Limited /M/s Cipla Limited	0.90	
4(viii)	Levetiracetam Infusion	Each 100ml contains: Levetiracetam IP 1000mg Sodium Chloride IP 750mg Water for Injections IP q. s.	1 ml	M/s Akums Drugs & Pharmaceuticals Limited /M/s Cipla Limited	1.44	
4(ix)	Bisoprolol Fumerate& Amlodipine Tablets	Each film coated tablet contains: Bisoprolol Fumerate IP 2.5mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Eris Lifesciences Limited	6.10	
4(x)	Bisoprolol Fumerate& Amlodipine Tablets	Each film coated tablet contains: Bisoprolol Fumerate IP 5mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Eris Lifesciences Limited	8.34	



Note: The Authority also noted that annexure to agenda item 4(ii) placed at page No. 129 is not correct. Pricing division clarified that inadvertently; page 132 is repeated and placed as page 129. However, the minutes of 47th MDC held on 05.12.2022 uploaded on NPPA's website have the correct annexure as placed at Page 203 of this agenda. Further, this has no impact on price recommended by MDC.

- 5. Agenda item no. 5 Status of implementation of Review cases
- 5.1 Noted.
- 6. Agenda item no. 6-Minutes of 47th Meeting of Multi Disciplinary Committee of Experts held on 02.12.2012
- 6.1 Noted
- 7. Agenda item no. 7 -Extension of revised price of Medical Oxygen
- 7.1 The Authority deliberated upon the matter and decided to extend the prices of Liquid Medical oxygen (LMO) and Oxygen Inhalation (Medical gas) in cylinder as notified vide SO No. 3322 (E)dated 25.9.2020 till 31st March, 2023 or fixation of prices under NLEM 2022, whichever is earlier.
- 8. Agenda item No. 8- Retail price Fixation of drugs under Phase IV clinical trial.
- 8.1 NPPA has received applications for retail price fixation in respect of drugs under Phase IV clinical trial. In this regard, Shri A.K. Pradhan, Jt. Drug Controller, CDSCO clarified that Phase IV Clinical trials are to be conducted by the companies for the drugs that are classified as "D" category drugs by Kokate Committee and the drugs are in market as per the approval of State Licensing Authorities (SLA), hence companies need to apply to DCGI for permission to conduct Phase IV clinical trial. NOC is issued subject to fulfillment of certain conditions by the company. However, since the drug is already approved by SLA and has to be in market, the retail price may be fixed by NPPA based on the copy of application submitted to DCGI for conducting Phase IV clinical trials/NOC issued by DCGI / license issued by DCGI, along with the Form I.
- Agenda item No. 9- Extension of validity of TMR notification pertaining to Oxygen Concentrator
- 9.1 The Authority deliberated upon the matter and decided that the prices of oxygen Concentrator as notified vide S.O. 2161 (E) dated 3rd June2021, S.O. 4909 (E) dated 30th November 2021, S.O. 2465 (E) dated 30th May 2022and 2983(E) dated 30th June 2022may be extended till 31st March, 2023 or till further order, whichever is earlier.
- 10. Agenda item No. 10- Extension of validity of TMR notification pertaining to 5 Medical Devices
- 10.1 The Authority deliberated upon the matter and decided that the prices of five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer as notified vide S.O.



2808(E) dated 13th July 2021, S.O. 401 (E) dated 31st January 2022 and S.O. 3534(E) dated 29th July 2022may be extended till 31st March, 2023 or till further order, whichever is earlier.

11. Agenda item no. 11(a)-Fixation of Ceiling Price of scheduled formulations under Revised Schedule-I (NLEM, 2022).

11.1 The Authority noted that the methodology for fixation of ceiling price of scheduled formulations under revised Schedule-I (NLEM, 2022) was deliberated in the 104th meeting of Authority held on 23.11.2022. Based on methodology approved, ceiling prices for 178 formulations were uploaded on NPPA website for 10 working days to invite comments in compliance to O.M. No. F. NO. 31015/44/2016-PI.I dated 11.07.2016 issued by Department of Pharmaceuticals as detailed in **Table 2**:

Table No. 2: Status of draft working sheets uploaded

S. No.	Date of upload of draft working sheets	10 days completed on	No. of formulations uploaded	No. of formulations approved in the meeting
1.	01.12.2022	15.12.2022	43	34
2.	02.12.2022	16.12.2022	51	46
3.	05.12.2022	19.12.2022	15	14
4.	13.12.2022	27.12.2022	69	3
	Total		178	97

11.2 The Authority was appraised that till date, 620 approx. representations from companies were received within the prescribed time lines of 10 days. Companies have submitted copy of invoice showing the revised PTR and snapshots of sample pack showing revised MRP. It was informed that these representations can be broadly categorized as under:

(a) Related to data in worksheets:

- Price to Retailer considered as per July, 2022 Pharmatrac database is not reflecting the WPI increase availed by the companies in April, 2022;
- ii. Incorrect pack sizes; and
- iii. Considering MR variant along with conventional variant in cases where MR variant is separately included in schedule.

(b) Related to methodology:

Representations received on methodology were same as already deliberated in 105th meeting of Authority held on 15.12.2022.

11.3 The Authority noted that the issues related to methodology as per the representations have been already deliberated and decided in 104th meeting of the authority. However, with regard to representations related to data, the Authority was informed that the claims made by the companies in their representations have been



cross verified with the Form-II/Form-V submitted by the companies till 15.05.2022 in IPDMS as per provisions of DPCO, 2013. The Authority also noted that 1% market share has been considered on the basis of Pharmatrac data base. Any other database, if quoted by any company in it's representation is not considered for assessment of 1% market share.

11.4 Authority noted that there was price revision in 74 formulations as compared to the ceiling prices reflected in the draft uploaded working sheets. The Authority deliberated and approved the ceiling prices of 97 formulations as appearing in column (7) of the Table 3 below:

Table 3: Ceiling Prices of 97 formulations

S.No.			Dosage form(s) and strength(s)	Prevail	ing Ceiling Price	New Ceiling Price with immediate effect	Unit
(1)	(2)	(3)	(3)	Rs. / Unit (5)	SO & dated (6)	(7)	(8)
1	2.4.4	Sulfasalazine	Tablet 500 mg	4.42	(S.O. 1499(E) dated 30.03.2022)	4.21	Per Tablet
2	10.4.1	Digoxin	Tablet 0.25mg	1.33	(S.O. 1499(E) dated 30.03.2022)	1.19	Per Tablet
3	6.4.7	Ethambutol	Tablet 600mg	3.93	(S.O. 1499(E) dated 30.03.2022)	3.64	Per Tablet
4	5.1.9	Phenytoin	Tablet 300mg	5.27	(S.O. 1499(E) dated 30.03.2022)	4.89	Per Tablet
5	6.7.4.1	Atazanavir (A) +Ritonavir(B)	Tablet 300mg(A)+Tablet100mg (B)	109.61	(S.O. 1499(E) dated 30.03.2022)	89.03	Per Tablet
6	6.2.1.11	Ceftriaxone	Powder for Injection 500 mg	50.06	(S.O. 1499(E) dated 30.03.2022)	44.84	Per Vial
7	6.2.1.11	Ceftriaxone	Powder for Injection 250 mg	27.4	(S.O. 1499(E) dated 30.03.2022)	25.28	Per Vial
8	6.2.1.11	Ceftriaxone	Powder for Injection 1000mg	59.86	(S.O. 1499(E) dated 30.03.2022)	55.64	Per Vial
9	6.2.1.11	Ceftriaxone	Powder for Injection 2000mg	142.29	(S.O. 1499(E) dated 30.03.2022)	123.18	Per Vial
10	6.2.1.9	Cefotaxime	Powder for Injection 250 mg	17.32	(S.O. 1499(E) dated 30.03.2022)	15.80	Per Vial
11	6.2.1.9	Cefotaxime	Powder for Injection 500 mg	22.78	(S.O. 1499(E) dated 30.03.2022)	21.74	Per Vial
12	6.2.1.9	Cefotaxime	Powder for Injection 1000mg	38.1	(S.O. 1499(E) dated 30.03.2022)	35.64	Per Vial
13	6.2.1.13	Piperacillin (A) +Tazobactam(B)	Powder for Injection 1000mg(A)+125mg(B)	98.15	(S.O. 1499(E) dated 30.03.2022)	88.88	Per Vial
14	6.2.1.13	Piperacillin (A) +Tazobactam(B)	Powder for Injection 2000mg(A)+250mg(B)	232.2	(S.O. 1499(E) dated 30.03.2022)	170.83	Per Vial
15	6.2.1.13	Piperacillin (A) +Tazobactam(B)	Powder for Injection 4000mg(A)+500mg(B)	487.76	(S.O. 1499(E) dated	356.21	Per Vial



S.No. Section		Formulations Dosage form(s) and strength(s)		Prevailing Ceiling Price		New Ceiling Price with immediate effect	Unit
(1)	(2)	(2) (3)	(4)	Rs. / Unit (5)	SO & dated (6)	(7)	(8)
					30.03.2022)		
16	6.2.1.3	Ampicillin	Powder for Injection 500 mg	14.6	(S.O. 1499(E) dated 30.03.2022)	12.71	Per Tablet
17	10.1.4	Metoprolol	Tablet 25mg	4.47	(S.O. 1499(E) dated 30.03.2022)	3.75	Per Tablet
18	10.1.4	Metoprolol	Tablet 50mg	6.41	(S.O. 1499(E) dated 30.03.2022)	5.21	Per Tablet
19	5.2.1.3	Propranolol	Tablet 40mg	3.06	(S.O. 1499(E) dated 30.03.2022)	2.87	Per Tablet
20	6.5.3	Fluconazole	Tablet 200mg	20.86	(S.O. 1499(E) dated 30.03.2022)	15.57	Per Tablet
21	6.4.7	Ethambutol	Tablet 800mg	4.7	(S.O. 1499(E) dated 30.03.2022)	4.42	Per Tablet
22	6.4.14	Pyrazinamide	Tablet 1000mg	10.47	(S.O. 1499(E) dated 30.03.2022)	9.39	Per Tablet
23	6.4.14	Pyrazinamide	Tablet 500mg	4.7	(S.O. 1499(E) dated 30.03.2022)	4.36	Per Tablet
24	6.4.14	Pyrazinamide	Tablet 750mg	7.14	(S.O. 1499(E) dated 30.03.2022)	6.43	Per Tablet
25	5.1.8	Phenobarbitone	Tablet 30mg	1.36	(S.O. 1499(E) dated 30.03.2022)	1.17	Per Tablet
26	10.2.2	Amiodarone	Tablet 200mg	12.57	(S.O. 1499(E) dated 30.03.2022)	10.27	Per Tablet
27	6.4.7	Ethambutol	Tablet 400mg	2.66	(S.O. 1499(E) dated 30.03.2022)	2.33	Per Tablet
28	6.5.3	Fluconazole	Tablet 100mg	8.86	(S.O. 1499(E) dated 30.03.2022)	6.80	Per Tablet
29	2.4.1	Azathioprine	Tablet 50mg	11.26	(S.O. 1499(E) dated 30.03.2022)	10.04	Per Tablet
30	2.3.1	Allopurinol	Tablet 100mg	2.12	(S.O. 1499(E) dated 30.03.2022)	1.69	Per Tablet
31	5.2.1.3	Propranolol	Tablet 10mg	1.3	(S.O. 1499(E) dated 30.03.2022)	1.17	Per Tablet
32	2.4.2	Hydroxychloroq uine	Tablet 200mg	6.58	(S.O. 1499(E) dated 30.03.2022)	5.67	Per Tablet
33	18.6.1	Carbimazole	Tablet10mg	4.11	(S.O. 1499(E) dated 30.03.2022)	3.80	Per Tablet
34	6.2.1.8	Cefixime	Tablet 200mg	10.66	(S.O. 1499(E) dated 30.03.2022)	8.72	Per Tablet



S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevail	ing Ceiling Price	New Ceiling Price with immediate effect	Unit
(1) (2)	(2)	(2) (3)	(4)	Rs. / Unit (5)	SO & dated (6)	(7)	(8)
35	7.1.25	Imatinib	Tablet 100mg	88.18	(S.O. 1499(E) dated 30.03.2022)	62.21	Per Tablet
36	7.2.5	Tamoxifen	Tablet 20mg	3.23	(S.O. 1499(E) dated 30.03.2022)	2.63	Per Tablet
37	7.2.5	Tamoxifen	Tablet 10mg	2.86	(S.O. 1499(E) dated 30.03.2022)	1.97	Per Tablet
38	7.1.27	L-Asparaginase	Powder for Injection 5000 KU	1150.5 6	(S.O. 1499(E) dated 30.03.2022)	922.94	Per Vial
39	7.1.27	L-Asparaginase	Powder for Injection10000KU	1782.4 7	(S.O. 1499(E) dated 30.03.2022)	1523.03	Per Vial
40	7.1.16	Dacarbazine	Powder for Injection 200mg	487.79	(S.O. 1499(E) dated 30.03.2022)	340.46	Per Vial
41	6.10.2.2	Mefloquine	Tablet 250 mg	56.6	(S.O. 1499(E) dated 30.03.2022)	46.52	Per Tablet
42	7.1.34	Thalidomide	Capsule 50 mg	39.19	(S.O. 1499(E) dated 30.03.2022)	27.79	Per Capsul e
43	7.1.35	Thalidomide	Capsule 100mg	67.84	(S.O. 1499(E) dated 30.03.2022)	55.31	Per Capsul e
44	23.3.1	Clonazepam	Tablet 0.25mg	2.03	(S.O. 1499(E) dated 30.03.2022)	1.80	Per Tablet
45	23.3.1	Clonazepam	Tablet 0.5mg	3.46	(S.O. 1499(E) dated 30.03.2022)	3.08	Per Tablet
46	23.3.1	Clonazepam	Tablet 1mg	4.70	(S.O. 1499(E) dated 30.03.2022)	4.25	Per Tablet
47	23.1.1	Clozapine	Tablet 25mg	2.79	(S.O. 1499(E) dated 30.03.2022)	2.48	Per Tablet
48	23.1.1	Clozapine	Tablet 50mg	5.34	(S.O. 1499(E) dated 30.03.2022)	4.63	Per Tablet
49	23.1.1	Clozapine	Tablet 100 mg	8.60	(S.O. 1499(E) dated 30.03.2022)	7.54	Per Tablet
50	6.2.2.9	Metronidazole	Tablet 200mg	0.76	(S.O. 1499(E) dated 30.03.2022)	0.73	Per Tablet
51	6.2.2.9	Metronidazole	Tablet 400mg	1.42	(S.O. 1499(E) dated 30.03.2022)	1.36	Per Tablet
52	7.1.23	Hydroxyurea	Capsule 500mg	14.23	(S.O. 1499(E) dated 30.03.2022)	10.81	Per Capsul e
53	2.1.3	Ibuprofen	Tablet 200mg	0.65	(S.O. 1499(E) dated 30.03.2022)	0.63	Per Tablet
54	21.4.1	Acetazolamide	Tablet 250mg	4.07	(S.O. 1499(E) dated	3.62	Per Tablet



S.No.	Section	ection Formulations (2) (3)	Dosage form(s) and strength(s)	Prevaili	ng Ceiling Price	New Ceiling Price with immediate effect	Unit
(1)	(2)		(4)	Rs. / Unit (5)	SO & dated (6)	(7)	(8)
					30.03.2022)		
55	6.2.2.3	Ciprofloxacin	Tablet 250mg	2.30	(S.O. 1499(E) dated 30.03.2022)	1.96	Per tablet
56	24.1.6	Salbutamol	Tablet 4 mg	0.20	(S.O. 1499(E) dated 30.03.2022)	0.19	Per Tablet
57	24.1.6	Salbutamol	Tablet 2 mg	0.18	(S.O. 1499(E) dated 30.03.2022)	0.16	Per Tablet
58	7.4.10	Metoclopramide	Tablet 10mg	1.30	(S.O. 1499(E) dated 30.03.2022)	1.20	Per Tablet
59	6.2.1.2	Amoxicillin (A) +Clavulanic acid (B)	Tablet 500 mg (A) + 125 mg (B)	19.95	(S.O. 1499(E) dated 30.03.2022)	16.32	Per Tablet
60	7.1.18	Docetaxel	Powder for Injection 20mg	3323.6 5	(S.O. 1499(E) dated 30.03.2022)	2558.14	Per Vial
61	6.8.5	Tenofovir Alafenamide Fumarate(TAF)	Tablet 25mg	New added	New added	43.59	Per Tablet
62	10.5.2	Clopidogrel	Tablet 75mg	7.72	(S.O. 1499(E) dated 30.03.2022)	5.94	Per Tablet
63	3.4	Hydrocortisone	Powder for Injection 100mg	43.21	(S.O. 1499(E) dated 30.03.2022)	39.95	Per Vial
64	7.1.22	Gemcitabine	Powder for Injection 1000mg	5890.6 5	(S.O. 1499(E) dated 30.03.2022)	4987.65	Per Vial
65	2.4.3	Methotrexate	Tablet 10mg	13.48	(S.O. 1499(E) dated 30.03.2022)	11.85	Per tablet
66	2.4.3	Methotrexate	Tablet 2.5mg	5.32	(S.O. 1499(E) dated 30.03.2022)	4.74	Per tablet
67	10.1.1	Diltiazem	Tablet 60mg	5.43	(S.O. 1499(E) dated 30.03.2022)	4.87	Per Tablet
68	10.2.1	Amiodarone	Tablet 100mg	6.35	(S.O. 1499(E) dated 30.03.2022)	5.48	Per Tablet
69	17.2.1	Domperidone	Tablet 10mg	2.68	(S.O. 1499(E) dated 30.03.2022)	2.06	Per Tablet
70	6.10.1.7	Quinine	Tablet 300 mg	6.36	(S.O. 1499(E) dated 30.03.2022)	5.04	Per Tablet
71	10.3.2	Enalapril	Tablet 5mg	3.57	(S.O. 1499(E) dated 30.03.2022)	3.30	Per Tablet
72	10.3.2	Enalapril	Tablet 2.5mg	2.15	(S.O. 1499(E) dated 30.03.2022)	1.95	Per Tablet
73	6.6.1.1	Acyclovir	Tablet 400mg	13.67	(S.O. 1499(E) dated 30.03.2022)	12.18	Per Tablet



S.No. Section		Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price with immediate effect	Unit
(1)	(2)	(2) (3)	(4)	Rs. / Unit (5)	SO & dated (6)	(7)	(8)
74	6.6.1.1	Acyclovir	Tablet 200mg	7.52	(S.O. 1499(E) dated 30.03.2022)	6.79	Per Tablet
75	6.4.15	Rifampicin	Capsule 450mg	5.48	(S.O. 1499(E) dated 30.03.2022)	5.06	Per Capsul e
76	6.7.1.9	Zidovudine (A) +Lamivudine(B)	Tablet 300mg(A)+150mg(B)	22.28	(S.O. 1499(E) dated 30.03.2022)	18.81	Per Tablet
77	6.10.1.6	Primaquine	Tablet 7.5mg	2.35	(S.O. 1499(E) dated 30.03.2022)	2.12	Per Tablet
78	6.2.2.10	Nitrofurantoin	Tablet 100 mg	8.03	(S.O. 1499(E) dated 30.03.2022)	7.23	Per Tablet
79	6.2.2.3	Ciprofloxacin	Tablet 500mg	4.05	(S.O. 1499(E) dated 30.03.2022)	3.79	Per tablet
80	7.4.14	Ondansetron	Tablet 8 mg	10.83	(S.O. 1499(E) dated 30.03.2022)	7.94	Per Tablet
81	6.5.4	Griseofulvin	Tablet 250mg	1.77	(S.O. 1499(E) dated 30.03.2022)	1.58	Per Tablet
82	23.2.1.2	Escitalopram	Tablet 5mg	5.06	(S.O. 1499(E) dated 30.03.2022)	4.48	Per Tablet
83	23.2.1.2	Escitalopram	Tablet 10mg	8.99	(S.O. 1499(E) dated 30.03.2022)	8.03	Per Tablet
84	23.2.1.2	Escitalopram	Tablet 20mg	14.21	(S.O. 1499(E) dated 30.03.2022)	12.81	Per Tablet
85	7.1.22	Gemcitabine	Powder for Injection 200 mg	1300.9 5	(S.O. 1499(E) dated 30.03.2022)	1159.21	Per Vial
86	6.2.1.10	Ceftazidime	Powder for Injection 1000mg	232.39	(S.O. 1499(E) dated 30.03.2022)	202.47	Per Vial
87	2.1.2	Diclofenac	Tablet 50mg	2.13	(S.O. 1499(E) dated 30.03.2022)	1.83	Per Tablet
88	5.1.1	Carbamazepine	Tablet 200mg	1.55	(S.O. 1499(E) dated 30.03.2022)	1.40	Per Tablet
39	6.2.1.2	Amoxicillin (A) +Clavulanic acid (B)	Powder for Injection 1 g (A) +200mg (B)	139.44	(S.O. 1499(E) dated 30.03.2022)	125.44	Per Vial
90	17.5.1	Bisacodyl	Tablet 5mg	1.12	(S.O. 1499(E) dated 30.03.2022)	1.04	Per Tablet
91	17.1.2	Pantoprazole	Injection 40mg	49.43	(S.O. 1499(E) dated 30.03.2022)	45.00	Each Vial
92	18.2.1.1	Ethinylestradiol (A)+Levonorgest rel(B)	Tablet 0.03mg(A)+Tablet0.15mg (B)	3.83	(S.O. 1499(E) dated 30.03.2022)	2.83	Per Tablet
93	18.5.2	Norethisterone	Tablet 5mg	5.67	(S.O. 1499(E) dated	4.81	Per Tablet



S.No.	Section (2)	Formulations (3)	Dosage form(s) and strength(s)	Prevail	ing Ceiling Price	New Ceiling Price with immediate effect	Unit
(1)				Rs. / Unit (5)	SO & dated (6)	(7)	
					30.03.2022)		
94	18.6.1	Carbimazole	Tablet 5mg	2.12	(S.O. 1499(E) dated 30.03.2022)	1.95	Per Tablet
95	23.5.2	Buprenorphine (A) +Naloxone (B)	Tablet (Sub- lingual)2mg(A)+0.5mg(B)	New added	New added	32.98	Per Tablet
96	23.5.2	Buprenorphine (A) +Naloxone (B)	Tablet (Sub- lingual)0.4mg(A)+0.1mg(B)	New added	New added	10.54	Per tablet
97	23.5.1	Buprenorphine	Tablet (Sub-lingual)0.4mg	New added	New added	8.41	Per tablet

Agenda item no. 11(b): Ceiling Prices of Sodium Valproate Tablet 300mg

11.5 The Authority deliberated upon the matter and decided to defer the agenda for revision of ceiling price of Sodium valproate Tablet 300mg notified on 19.12.2022. The Authority also directed that all the price fixation cases of scheduled formulations of sodium valproate may be placed before the Authority together. Further, the ceiling prices for Sodium valproate Tablet 300mg shall continue to prevail as notified on 19.12.2022 vide SO 5938 (E) until further order.

Agenda item no. 11(c): Revision of Ceiling Price fixed in 105th Authority meeting held on 15.12.2022 and notified on 19.12.2022 of 31 scheduled formulations under Revised Schedule-I (NLEM, 2022)

11.6 The Authority deliberated upon the matter in detail and noted that companies have complied with DPCO provisions and submitted Form II within the prescribed time as mentioned in DPCO 2013. Accordingly, the Authority decided that in respect of following 31 formulations as given in **Table 4**, prices may be revised as mentioned in column (7) and corrigendum may be issued for the prices notified vide SO No. 5938 and 5939 dated 19.12.2022 for these 31 formulations.

Table 4: Revision of ceiling price of 31 formulations

S. No.		Formulation (3)	Dosage form(s) and strength(s)	Notified Ceiling Price		Revised Ceiling Price	Unit
(1)				Rs. / Unit (5)	SO & dated (6)	(7)	(8)
1	10.3.7	Telmisartan	Tablet 80mg	9.24	5938(E) dt. 19.12.2022	9.28	Per Tablet
2	5.4.1	Donepezil	Tablet 5mg	10.57	5938(E) dt. 19.12.2022	10.80	Per Tablet
3	5.4.1	Donepezil	Tablet 10mg	15.24	5938(E) dt. 19.12.2022	15.57	Per Tablet



S. No.	Section (2)	Formulation (3)	Dosage form(s) and strength(s)	Notified Ceiling Price		Revised Ceiling Price	Unit
(1)				Rs. / Unit (5)	SO & dated (6)	(7)	(8)
4	10.3.7	Telmisartan	Tablet 20mg	3.44	5938(E) dt. 19.12.2022	3.46	Per Table
5	10.3.1	Amlodipine	Tablet 10mg	4.81	5938(E) dt. 19.12.2022	4.86	Per Table
6	18.3.1.1	Glimepiride	Tablet 1mg	3.27	5938(E) dt. 19.12.2022	3.30	Per Table
7	6.4.12	Moxifloxacin	Tablet 400mg	22.79	5938(E) dt. 19.12.2022	23.03	Per Table
8	5.1.4	Levetiracetam	Tablet 750mg	16.98	5938(E) dt. 19.12.2022	17.25	Per Table
9	18.3.1.1	Glimepiride	Tablet 2mg	5.11	5938(E) dt. 19.12.2022	5.17	Per Table
10	6.2.2.4	Clarithromycin	Tablet 250mg	21.04	5938(E) dt. 19.12.2022	21.31	Per Tablet
11	6.4.10	Levofloxacin	Tablet 500mg	7.85	5938(E) dt. 19.12.2022	8.02	Per Tablet
12	1.4.2	Baclofen	Tablet 10mg	10.39	5938(E) dt. 19.12.2022	10.61	Per Table
13	6.4.10	Levofloxacin	Tablet 250mg	4.25	5938(E) dt. 19.12.2022	4.30	Per Table
14	2.1.5	Paracetamol	Tablet650m g	1.78	5938(E) dt. 19.12.2022	1.79	Per Table
15	10.3.1	Amlodipine	Tablet 2.5mg	1.59	5938(E) dt. 19.12.2022	1.60	Per Table
16	5.1.4	Levetiracetam	Tablet 250mg	5.57	5938(E) dt. 19.12.2022	5.62	Per Table
17	6.2.2.4	Clarithromycin	Tablet 500mg	34.61	5938(E) dt. 19.12.2022	35.53	Per Table
18	5.1.2	Clobazam	Tablet 10mg	8.55	5938(E) dt. 19.12.2022	8.78	Per Table
19	23.1.4	Risperidone	Tablet 1 mg	2.66	5938(E) dt. 19.12.2022	2.70	Per Table
20	23.3.2	Zolpidem	Tablet 5mg	5.44	5938(E) dt. 19.12.2022	5.54	Per Table
21	6.4.10	Levofloxacin	Tablet 750mg	10.69	5938(E) dt. 19.12.2022	11.10	Per Table
22	10.6.1	Atorvastatin	Tablet 40mg	16.92	5938(E) dt. 19.12.2022	17.21	Per Table
23	5.2.1.1	Amitriptyline	Tablet 75mg	4.77	5938(E) dt. 19.12.2022	4.86	Per Table
24	10.6.1	Atorvastatin	Tablet 10mg	4.38	5938(E) dt. 19.12.2022	4.41	Per Table
25	10.6.1	Atorvastatin	Tablet 20mg	11.01	5938(E) dt. 19.12.2022	11.20	Per Table
26	5.2.1.1	Amitriptyline	Tablet 25mg	2.16	5938(E) dt. 19.12.2022 5938(E) dt.	2.22	Per Tablet Per
27	5.1.2	Clobazam	Tablet 5mg Tablet	4.94	19.12.2022	5.11	Table:
28	7.4.7	Haloperidol	1.5mg Tablet	1.37	5938(E) dt. 19.12.2022	1.41	Tablet Per
29	18.3.1.6	Metformin	500mg	1.77	5938(E) dt. 19.12.2022	1.80	Table



S. No.	Section	Formulation	Dosage form(s) and strength(s)	Notified Ceiling Price		Revised Ceiling Price	Unit
(1)	(2)	(3)		Rs. / Unit (5)	SO & dated (6)	(7)	(8)
30	18.3.1.6	Metformin	Modified release Tablet 1000mg	3.52	5938(E) dt. 19.12.2022	3.61	Per Tablet
31	5.1.4	Levetiracetam	Tablet 500mg	11.40	5938(E) dt. 19.12.2022	11.58	Per Tablet

12. Agenda item no. 12-Fixation of Ceiling Price of Coronary Stents under Revised Schedule-I (NLEM, 2022).

12.1 It was informed to the Authority that Ministry of Health and Family Welfare, Government of India has included Coronary Stents in the National List of Essential Medicines, 2022 (NLEM, 2022) vide notification No X-11035/346/2021-DRS dated 10th November, 2022. The Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India by notification No. S.O. 5249 (E) dated 11th November 2022 has incorporated Coronary Stents at Section 28 of the revised Schedule I of the Drug Prices Control Order, 2013 (DPCO,2013) and therefore, Coronary Stents are 'scheduled formulation' under the provisions of the DPCO, 2013. The categories of Coronary Stents included in the Schedule I of the DPCO 2013 are reproduced below:

Section 28.1: Bare Metal Stents (BMS)

Section 28.2: Drug Eluting Stents (DES) which include metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable stents"

12.2 Therefore, the NPPA has to refix the ceiling prices of the coronary stents as per the provisions of the DPCO, 2013. NPPA has carried out an exhaustive exercise of data collection from the manufacturers as well as importers of coronary stents in November/December 2022.

12.3 The Authority deliberated upon the matter in detail and directed that further analysis is required & decided to defer the matter.

The meeting ended with a vote of thanks to the Chair and all the participants in the meeting.

(Dr. Vinod Kotwal) Member Secretary